

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 1**ORGANIZATIONAL DUNS*:** 0948783370000**Budget Type*:** ☐ Project ☒ Subaward/Consortium**Enter name of Organization:** The Regents of the University of California at San Francisco**Start Date*:** 07-01-2015**End Date*:** 06-30-2016**Budget Period:** 1

A. Senior/Key Person													
Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary (\$)	Calendar Months	Academic Months	Summer Months	Requested Salary (\$)*	Fringe Benefits (\$)*	Funds Requested (\$)*	
1 . Dr.	Stephen		Rosenthal	MD	PD/PI					36,300.00	11,979.00	48,279.00	
2 . Dr.	Diane		Ehrensaft	PhD	Co-Investigator					25,713.00	11,056.00	36,769.00	
3 . Dr.	David		Glidden	PhD	Co-Investigator					9,075.00	3,358.00	12,433.00	
Total Funds Requested for all Senior Key Persons in the attached file													
Additional Senior Key Persons:		File Name:										Total Senior/Key Person	97,481.00

B. Other Personnel							
Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary (\$)*	Fringe Benefits*	Funds Requested (\$)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Study Coordinator				21,933.00	9,431.00	31,364.00
1	Clinical Research Nurse				14,315.00	6,155.00	20,470.00
2	Total Number Other Personnel					Total Other Personnel	51,834.00
						Total Salary, Wages and Fringe Benefits (A+B)	149,315.00

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 1**ORGANIZATIONAL DUNS*:** 0948783370000**Budget Type*:** ☐ Project ☒ Subaward/Consortium**Organization:** The Regents of the University of California at San Francisco**Start Date*:** 07-01-2015**End Date*:** 06-30-2016**Budget Period:** 1**C. Equipment Description**

List items and dollar amount for each item exceeding \$5,000

Equipment Item**Funds Requested (\$)*****Total funds requested for all equipment listed in the attached file****Total Equipment****Additional Equipment:** File Name:**D. Travel****Funds Requested (\$)***

1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)

2. Foreign Travel Costs

Total Travel Cost**E. Participant/Trainee Support Costs****Funds Requested (\$)***

1. Tuition/Fees/Health Insurance

2. Stipends

3. Travel

4. Subsistence

5. Other:

Number of Participants/Trainees**Total Participant Trainee Support Costs**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 1**ORGANIZATIONAL DUNS*:** 0948783370000**Budget Type*:** ☐ Project ☒ Subaward/Consortium**Organization:** The Regents of the University of California at San Francisco**Start Date*:** 07-01-2015**End Date*:** 06-30-2016**Budget Period:** 1

F. Other Direct Costs	Funds Requested (\$)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Data Network Recharge	414.00
9 . CCDSS	869.00
Total Other Direct Costs	1,283.00

G. Direct Costs	Funds Requested (\$)*
Total Direct Costs (A thru F)	150,598.00

H. Indirect Costs			
Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	Funds Requested (\$)*
1 . Modified Total Direct Costs	58.50	150,598.00	88,100.00
		Total Indirect Costs	88,100.00
Cognizant Federal Agency	DHHS, Jeanette Lu, 415-437-7820		
(Agency Name, POC Name, and POC Phone Number)			

I. Total Direct and Indirect Costs	Funds Requested (\$)*
Total Direct and Indirect Institutional Costs (G + H)	238,698.00

J. Fee	Funds Requested (\$)*

K. Budget Justification*	File Name: 1243-UCSF Budget Justification.pdf (Only attach one file.)
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RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 2**ORGANIZATIONAL DUNS*:** 0948783370000**Budget Type*:** ☐ Project ☒ Subaward/Consortium**Enter name of Organization:** The Regents of the University of California at San Francisco**Start Date*:** 07-01-2016**End Date*:** 06-30-2017**Budget Period:** 2

A. Senior/Key Person													
Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary (\$)	Calendar Months	Academic Months	Summer Months	Requested Salary (\$)*	Fringe Benefits (\$)*	Funds Requested (\$)*	
1 . Dr.	Stephen		Rosenthal	MD	PD/PI					36,300.00	12,705.00	49,005.00	
2 . Dr.	Diane		Ehrensaft	PhD	Co-Investigator					25,713.00	11,571.00	37,284.00	
3 . Dr.	David		Glidden	PhD	Co-Investigator					9,075.00	3,539.00	12,614.00	
Total Funds Requested for all Senior Key Persons in the attached file													
Additional Senior Key Persons:			File Name:								Total Senior/Key Person		98,903.00

B. Other Personnel								
Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary (\$)*	Fringe Benefits*	Funds Requested (\$)*	
	Post Doctoral Associates							
	Graduate Students							
	Undergraduate Students							
	Secretarial/Clerical							
1	Study Coordinator				31,279.00	14,076.00	45,355.00	
1	Data Manager				11,585.00	5,213.00	16,798.00	
1	Clinical Research Nurse				29,489.00	13,270.00	42,759.00	
3	Total Number Other Personnel					Total Other Personnel		104,912.00
					Total Salary, Wages and Fringe Benefits (A+B)		203,815.00	

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 2**ORGANIZATIONAL DUNS*:** 0948783370000**Budget Type*:** ☐ Project ☒ Subaward/Consortium**Organization:** The Regents of the University of California at San Francisco**Start Date*:** 07-01-2016**End Date*:** 06-30-2017**Budget Period:** 2**C. Equipment Description**

List items and dollar amount for each item exceeding \$5,000

Equipment Item**Funds Requested (\$)*****Total funds requested for all equipment listed in the attached file****Total Equipment****Additional Equipment:** File Name:**D. Travel****Funds Requested (\$)***

1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)

2. Foreign Travel Costs

Total Travel Cost**E. Participant/Trainee Support Costs****Funds Requested (\$)***

1. Tuition/Fees/Health Insurance

2. Stipends

3. Travel

4. Subsistence

5. Other:

Number of Participants/Trainees**Total Participant Trainee Support Costs**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 2**ORGANIZATIONAL DUNS*:** 0948783370000**Budget Type*:** ☐ Project ☒ Subaward/Consortium**Organization:** The Regents of the University of California at San Francisco**Start Date*:** 07-01-2016**End Date*:** 06-30-2017**Budget Period:** 2

F. Other Direct Costs	Funds Requested (\$)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Data Network Recharge	682.00
9 . CCDSS	1,426.00
Total Other Direct Costs	2,108.00

G. Direct Costs	Funds Requested (\$)*
Total Direct Costs (A thru F)	205,923.00

H. Indirect Costs			
Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	Funds Requested (\$)*
1 . Modified Total Direct Costs	58.50	205,923.00	120,465.00
		Total Indirect Costs	120,465.00
Cognizant Federal Agency	DHHS, Jeanette Lu, 415-437-7820		
(Agency Name, POC Name, and POC Phone Number)			

I. Total Direct and Indirect Costs	Funds Requested (\$)*
Total Direct and Indirect Institutional Costs (G + H)	326,388.00

J. Fee	Funds Requested (\$)*

K. Budget Justification*	File Name: 1243-UCSF Budget Justification.pdf (Only attach one file.)
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RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 3**ORGANIZATIONAL DUNS*:** 0948783370000**Budget Type*:** ☐ Project ☒ Subaward/Consortium**Enter name of Organization:** The Regents of the University of California at San Francisco**Start Date*:** 07-01-2017**End Date*:** 06-30-2018**Budget Period:** 3

A. Senior/Key Person												
Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary (\$)	Calendar Months	Academic Months	Summer Months	Requested Salary (\$)*	Fringe Benefits (\$)*	Funds Requested (\$)*
1 . Dr.	Stephen		Rosenthal	MD	PD/PI					36,300.00	13,431.00	49,731.00
2 . Dr.	Diane		Ehrensaft	PhD	Co-Investigator					25,713.00	12,085.00	37,798.00
3 . Dr.	David		Glidden	PhD	Co-Investigator					9,075.00	3,721.00	12,796.00
Total Funds Requested for all Senior Key Persons in the attached file												
Additional Senior Key Persons:			File Name:							Total Senior/Key Person		100,325.00

B. Other Personnel								
Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary (\$)*	Fringe Benefits*	Funds Requested (\$)*	
	Post Doctoral Associates							
	Graduate Students							
	Undergraduate Students							
	Secretarial/Clerical							
1	Study Coordinator				32,218.00	15,142.00	47,360.00	
1	Data Manager				11,932.00	5,608.00	17,540.00	
1	Clinical Research Nurse				30,374.00	14,276.00	44,650.00	
3	Total Number Other Personnel					Total Other Personnel		109,550.00
					Total Salary, Wages and Fringe Benefits (A+B)		209,875.00	

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 3**ORGANIZATIONAL DUNS*:** 0948783370000**Budget Type*:** ☐ Project ☒ Subaward/Consortium**Organization:** The Regents of the University of California at San Francisco**Start Date*:** 07-01-2017**End Date*:** 06-30-2018**Budget Period:** 3**C. Equipment Description**

List items and dollar amount for each item exceeding \$5,000

Equipment Item**Funds Requested (\$)*****Total funds requested for all equipment listed in the attached file****Total Equipment****Additional Equipment:** File Name:**D. Travel****Funds Requested (\$)***

1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)

2. Foreign Travel Costs

Total Travel Cost**E. Participant/Trainee Support Costs****Funds Requested (\$)***

1. Tuition/Fees/Health Insurance

2. Stipends

3. Travel

4. Subsistence

5. Other:

Number of Participants/Trainees**Total Participant Trainee Support Costs**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 3**ORGANIZATIONAL DUNS*:** 0948783370000**Budget Type*:** ☐ Project ☒ Subaward/Consortium**Organization:** The Regents of the University of California at San Francisco**Start Date*:** 07-01-2017**End Date*:** 06-30-2018**Budget Period:** 3

F. Other Direct Costs	Funds Requested (\$)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Data Network Recharge	729.00
9 . CCDSS	1,519.00
Total Other Direct Costs	2,248.00

G. Direct Costs	Funds Requested (\$)*
Total Direct Costs (A thru F)	212,123.00

H. Indirect Costs			
Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	Funds Requested (\$)*
1 . Modified Total Direct Costs	58.50	212,123.00	124,092.00
		Total Indirect Costs	124,092.00
Cognizant Federal Agency	DHHS, Jeanette Lu, 415-437-7820		
(Agency Name, POC Name, and POC Phone Number)			

I. Total Direct and Indirect Costs	Funds Requested (\$)*
Total Direct and Indirect Institutional Costs (G + H)	336,215.00

J. Fee	Funds Requested (\$)*

K. Budget Justification*	File Name: 1243-UCSF Budget Justification.pdf (Only attach one file.)
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RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 4**ORGANIZATIONAL DUNS*:** 0948783370000**Budget Type*:** ☐ Project ☒ Subaward/Consortium**Enter name of Organization:** The Regents of the University of California at San Francisco**Start Date*:** 07-01-2018**End Date*:** 06-30-2019**Budget Period:** 4

A. Senior/Key Person												
Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary (\$)	Calendar Months	Academic Months	Summer Months	Requested Salary (\$)*	Fringe Benefits (\$)*	Funds Requested (\$)*
1 . Dr.	Stephen		Rosenthal	MD	PD/PI					36,300.00	14,157.00	50,457.00
2 . Dr.	Diane		Ehrensaft	PhD	Co-Investigator					25,713.00	12,599.00	38,312.00
3 . Dr.	David		Glidden	PhD	Co-Investigator					9,075.00	3,902.00	12,977.00
Total Funds Requested for all Senior Key Persons in the attached file												
Additional Senior Key Persons:			File Name:							Total Senior/Key Person		101,746.00

B. Other Personnel							
Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary (\$)*	Fringe Benefits*	Funds Requested (\$)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Study Coordinator				33,184.00	15,597.00	48,781 00
1	Data Manager				12,290.00	5,777.00	18,067 00
1	Clinical Research Nurse				31,285.00	14,704.00	45,989 00
3	Total Number Other Personnel	Total Other Personnel					112,837.00
					Total Salary, Wages and Fringe Benefits (A+B)		214,583.00

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 4**ORGANIZATIONAL DUNS*:** 0948783370000**Budget Type*:** ☐ Project ☒ Subaward/Consortium**Organization:** The Regents of the University of California at San Francisco**Start Date*:** 07-01-2018**End Date*:** 06-30-2019**Budget Period:** 4**C. Equipment Description**

List items and dollar amount for each item exceeding \$5,000

Equipment Item**Funds Requested (\$)*****Total funds requested for all equipment listed in the attached file****Total Equipment****Additional Equipment:** File Name:**D. Travel****Funds Requested (\$)***

1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)

2. Foreign Travel Costs

Total Travel Cost**E. Participant/Trainee Support Costs****Funds Requested (\$)***

1. Tuition/Fees/Health Insurance

2. Stipends

3. Travel

4. Subsistence

5. Other:

Number of Participants/Trainees**Total Participant Trainee Support Costs**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 4**ORGANIZATIONAL DUNS*:** 0948783370000**Budget Type*:** ☐ Project ☒ Subaward/Consortium**Organization:** The Regents of the University of California at San Francisco**Start Date*:** 07-01-2018**End Date*:** 06-30-2019**Budget Period:** 4

F. Other Direct Costs	Funds Requested (\$)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Data Network Recharge	729.00
9 . CCDSS	1,519.00
Total Other Direct Costs	2,248.00

G. Direct Costs	Funds Requested (\$)*
Total Direct Costs (A thru F)	216,831.00

H. Indirect Costs			
Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	Funds Requested (\$)*
1 . Modified Total Direct Costs	58.50	216,831.00	126,846.00
		Total Indirect Costs	126,846.00
Cognizant Federal Agency	DHHS, Jeanette Lu, 415-437-7820		
(Agency Name, POC Name, and POC Phone Number)			

I. Total Direct and Indirect Costs	Funds Requested (\$)*
Total Direct and Indirect Institutional Costs (G + H)	343,677.00

J. Fee	Funds Requested (\$)*

K. Budget Justification*	File Name: 1243-UCSF Budget Justification.pdf (Only attach one file.)
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RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 5**ORGANIZATIONAL DUNS*:** 0948783370000**Budget Type*:** ☐ Project ☒ Subaward/Consortium**Enter name of Organization:** The Regents of the University of California at San Francisco**Start Date*:** 07-01-2019**End Date*:** 06-30-2020**Budget Period:** 5

A. Senior/Key Person												
Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary (\$)	Calendar Months	Academic Months	Summer Months	Requested Salary (\$)*	Fringe Benefits (\$)*	Funds Requested (\$)*
1 . Dr.	Stephen		Rosenthal	MD	PD/PI					36,300.00	14,883.00	51,183.00
2 . Dr.	Diane		Ehrensaft	PhD	Co-Investigator					25,713.00	13,113.00	38,826.00
3 . Dr.	David		Glidden	PhD	Co-Investigator					9,075.00	4,084.00	13,159.00
Total Funds Requested for all Senior Key Persons in the attached file												
Additional Senior Key Persons:		File Name:									Total Senior/Key Person	103,168.00

B. Other Personnel							
Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary (\$)*	Fringe Benefits*	Funds Requested (\$)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Study Coordinator				34,180.00	16,348.00	50,528.00
1	Data Manager				12,659.00	6,055.00	18,714.00
1	Clinical Research Nurse				32,223.00	15,412.00	47,635.00
3	Total Number Other Personnel					Total Other Personnel	116,877.00
Total Salary, Wages and Fringe Benefits (A+B)						220,045.00	

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 5**ORGANIZATIONAL DUNS*:** 0948783370000**Budget Type*:** ☐ Project ☒ Subaward/Consortium**Organization:** The Regents of the University of California at San Francisco**Start Date*:** 07-01-2019**End Date*:** 06-30-2020**Budget Period:** 5**C. Equipment Description**

List items and dollar amount for each item exceeding \$5,000

Equipment Item**Funds Requested (\$)*****Total funds requested for all equipment listed in the attached file****Total Equipment****Additional Equipment:** File Name:**D. Travel****Funds Requested (\$)***

1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)

2. Foreign Travel Costs

Total Travel Cost**E. Participant/Trainee Support Costs****Funds Requested (\$)***

1. Tuition/Fees/Health Insurance

2. Stipends

3. Travel

4. Subsistence

5. Other:

Number of Participants/Trainees**Total Participant Trainee Support Costs**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 5**ORGANIZATIONAL DUNS*:** 0948783370000**Budget Type*:** ☐ Project ☒ Subaward/Consortium**Organization:** The Regents of the University of California at San Francisco**Start Date*:** 07-01-2019**End Date*:** 06-30-2020**Budget Period:** 5

F. Other Direct Costs	Funds Requested (\$)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Data Network Recharge	729.00
9 . CCDSS	1,519.00
Total Other Direct Costs	2,248.00

G. Direct Costs	Funds Requested (\$)*
Total Direct Costs (A thru F)	222,293.00

H. Indirect Costs			
Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	Funds Requested (\$)*
1 . Modified Total Direct Costs	58.50	222,293.00	130,041.00
		Total Indirect Costs	130,041.00
Cognizant Federal Agency	DHHS, Jeanette Lu, 415-437-7820		
(Agency Name, POC Name, and POC Phone Number)			

I. Total Direct and Indirect Costs	Funds Requested (\$)*
Total Direct and Indirect Institutional Costs (G + H)	352,334.00

J. Fee	Funds Requested (\$)*

K. Budget Justification*	File Name: 1243-UCSF Budget Justification.pdf (Only attach one file.)
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RESEARCH & RELATED Budget {F-K} (Funds Requested)

BUDGET JUSTIFICATION: UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

Salaries: Pursuant to University of California (UC) policy, salaries in the initial budget period are based on current published UC salary scales and include University mandated range adjustments and merit increases scheduled to occur before the proposed project start date. Pay rate increases in FY02 through FY05 are based on merit review schedules established by UCSF Academic Affairs.

A. Senior/Key Personnel

Stephen M. Rosenthal, M.D., Site Principal Investigator (■■■ Calendar Months (CM) Y1-Y5)

Qualifications: Dr. Rosenthal is Professor of Pediatrics at UCSF, Program Director for Pediatric Endocrinology, Co-Director of the Disorders of Sex Development Clinic, and founder and Medical Director of the UCSF Child and Adolescent Gender Center (CAGC). The UCSF CAGC serves as the Pediatric/Adolescent clinical arm of the widely recognized UCSF Center of Excellence for Transgender Health. The CAGC provides multi-disciplinary care to gender non-conforming/transgender youth and adolescents and is the only such multi-disciplinary gender program in Northern California, attracting patients not only from California, but from as far away as Alaska, Florida, and Egypt. Dr. Rosenthal has been appointed as the official representative of the Pediatric Endocrine Society (PES) to the Endocrine Society's (ES) Clinical Practice Guidelines Revision Task Force for the Care of Transgender Individuals and was appointed to the World Professional Association for Transgender Health (WPATH) Consensus committee for revisions of the International Classification of Disease (ICD)-11 pertaining to transgender youth and adults. Dr. Rosenthal has authored seven manuscripts on transgender youth, including a recent "State-of-the-art" invited review in *Pediatrics* and an invited review in the "Approach to the Patient" series for the *Journal of Clinical Endocrinology and Metabolism*. Dr. Rosenthal has been an invited speaker on transgender youth at annual meetings of PES and ES, as well as at the most recent international meeting of WPATH, and has lectured on this subject at academic centers throughout the U.S. Dr. Rosenthal is also the recipient of the UCSF Chancellor Award for LGBT leadership in recognition of his work with transgender youth and is the recipient of the UCSF Family Advisory Council Caring Tree Award and the UCSF Haile T. Debas Academy of Medical Educators Excellence in Teaching Award. Dr. Rosenthal is an established clinical investigator with greater than 30 years' experience in child and adolescent endocrinology and has significant experience conducting multi-center trials. He is currently serving as site PI for NIH/NICHD Disorders of Sex Development: Platform for Basic and Translational Research (1R01HD068138-01A1).

Role on Project: Dr. Rosenthal will have primary responsibility for the implementation of the scientific aims of this project at UCSF. He will collaborate in protocol development (in particular, the endocrine/metabolic parameters), data analysis, and dissemination of findings. **Total Salary Requested Y1-5: \$181,500**

Diane Ehrensaft, Ph.D., Co-Investigator and Psychologist (■■■ CM Y1- Y5)

Qualifications: Dr. Ehrensaft is Associate Professor of Pediatrics at UCSF and Mental Health Director of the UCSF Child and Adolescent Gender Center. She is a developmental and clinical psychologist and an internationally recognized child and adolescent gender specialist.

Role on Project: Dr. Ehrensaft will have a primary role in the design and implementation of mental health measures and will collaborate in data analysis and dissemination of findings. **Total Salary Requested Y1-5: \$128,565**

David V. Glidden, Ph.D., Biostatistician (■■■ CM Y1-Y5)

Qualifications: Dr. Glidden is Professor of Biostatistics at UCSF. He received his Ph.D. from the University of Washington in 1993 and spent four years at the Department of Biostatistics at the Harvard School of Public Health before joining the UCSF faculty in 1997. He has experience in developing methods for data analysis, has been an author of an intermediate textbook (Regression Methods in Biostatistics, Spring, 2nd edition, 2011), and has long experience collaborating with investigators in diverse medical specialties. He also has extensive experience in clinical trials, having been the lead statistician for a pivotal study (Grant et al, 2010; for which he was senior author) for chemoprophylaxis for the prevention of HIV acquisition. He is experienced in the analysis of longitudinal data.

Role on Project: Dr. Glidden will work as a resource for Dr. Schrager, Biostatistician at the Core Site, and will provide advice and support on analytic approaches. He will focus the bulk of his activities on the analysis of the

metabolic data. He will be responsible for the design, analysis plan development, and execution of these analyses. **Total Salary Requested Y1-5: \$45,375**

B. Other Personnel

To Be Named, Study Coordinator [REDACTED] CM Y1; 5.4 CM Y2-Y5)

Role on Project: The Study Coordinator will meet regularly with project investigators and will coordinate project development, participant recruitment, and overall project implementation. He/she will also work with the site PI to coordinate all Institutional Review Board (IRB)-related communications and will manage day-to-day operations of the project. **Total Salary Requested Y1-5: \$152,794**

To Be Named, Data Manager [REDACTED] CM Y2-Y5)

Role on Project: The Data Manager will program computerized data collection and provide data management support, including maintenance of research records, preparation of progress reports, and assistance with IRB submissions. The Data Manager will also assist in the preparation of manuscripts and conference presentations. **Total Salary Requested Y1-5: \$48,466**

To Be Named, Clinical Research Nurse [REDACTED] CM Y1; 3.0 CM Y2-Y5)

Role on Project: The Clinical Research Nurse (Registered Nurse degree or more advanced) will conduct study-related research visits in collaboration with study investigators and will assist with collection of study-related specimens and regulatory documentation. **Total Salary Requested Y1-5: \$137,686**

Fringe Benefits

Fringe Benefits include health and life insurance, social security, Medicare, dental plan, vision, unemployment insurance, non-industrial disability insurance, worker's compensation insurance, and retirement. Our request is based on actual fringe rates for current employees, which varies according to each person's benefit enrollments. Fringe benefits for TBN employees are [REDACTED] of salaries for staff personnel, as of July 1, 2015. Fringe benefits for current and TBN employees escalate by 2% each year, based on campus budget projections and consistent with guidance from the University of California, San Francisco (UCSF) Office of Sponsored Research. Total Fringe Benefits are: Year 1 \$41,979; Year 2 \$60,374; Year 3 \$64,263; Year 4 \$66,736; Year 5 \$69,895. **Total Fringe Benefits Requested Y1-Y5: \$303,247**

C. Equipment

No Equipment in excess of \$5,000 per item will be purchased.

D. Travel

No Travel is requested.

E. Participant/Trainee Support Costs

No Participant/Trainee Supports Costs are being requested.

F. Other Direct Costs

UCSF Data Network Recharge: Effective November 1, 2009 the Chancellor's Executive Committee approved a UCSF data network services recharge. The recharge provides funding for critical equipment in support of the campus network. The funding model for data network service includes a UCSF-wide per capita recharge of \$41/month/FTE. The rate increases in future years, as follows: 7/1/16-6/30/17: \$44/month/FTE and \$47/month/FTE from 7/1/17 until amended. As permissible by OMB A-21 and per review and agreement

by our cognizant federal agency, UCSF data network costs are an allowable direct expense. **Total UCSF Data Network Recharge Requested: \$3,283**

Computing and Communication Device Support Services (CCDSS): CCDSS provides integral support to campus voice and data technology functions. CCDSS includes software installation/updates, internet security, hardware setup/configuration, and centrally managed patching, storage and backup. The university charges these expenses to all funding sources based on a monthly recharge rate per FTE, consistent with the university's current methodology used for data network services. The recharge rates are provided for under our approved DS-2, will be computed in accordance with applicable OMB requirements, including 2 CFR Part 220 (formerly Circular A-21), and will be reviewed and adjusted annually. **Total Computing and Communication Device Support Services Requested: \$6,852**

G. Total Direct Costs

Total Direct Costs are as follows:

	Direct
Year 1	\$150,598
Year 2	\$205,923
Year 3	\$212,123
Year 4	\$216,831
Year 5	\$222,293
TOTAL	\$1,007,768

H. Indirect Costs

Indirect costs (Facilities & Administrative Costs) are based on Modified Total Direct Costs and are 58.5% in Years 1 - 5 as approved by the Department of Health and Human Services.

Year 1	\$88,100
Year 2	\$120,465
Year 3	\$124,092
Year 4	\$126,846
Year 5	\$130,041
TOTAL	\$589,544

I. Total Direct and Indirect Costs

	TOTAL Per Year
Year 1	\$238,698
Year 2	\$326,388
Year 3	\$336,215
Year 4	\$343,677
Year 5	\$352,334
TOTAL	\$1,597,312

J. Fee

No Fee is being requested.

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals (\$)	
Section A, Senior/Key Person		501,623.00
Section B, Other Personnel		496,010.00
Total Number Other Personnel	14	
Total Salary, Wages and Fringe Benefits (A+B)		997,633.00
Section C, Equipment		
Section D, Travel		
1. Domestic		
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs		10,135.00
1. Materials and Supplies		
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1	3,283.00	
9. Other 2	6,852.00	
10. Other 3		
Section G, Direct Costs (A thru F)		1,007,768.00
Section H, Indirect Costs		589,544.00
Section I, Total Direct and Indirect Costs (G + H)		1,597,312.00
Section J, Fee		

Research Subaward Agreement Amendment

Pass-Through Entity (PTE)	Subrecipient
Children's Hospital Los Angeles	Entity Name: The Regents of University of California, San Francisco
4650 Sunset Boulevard, Los Angeles, CA 90027-6062	Address including City, State, Zip+4 (Country, if non-US): 3333 California Street, Suite 315 San Francisco, CA 94118
Johanna Olson	Principal Investigator: Stephen Rosenthal
PTE Federal Award No: 5R01HD082554-03	Amendment No: 1 Federal Awarding Agency: NIH-NICHD

Project Title: The Impact of Early Medical Treatment in Transgender Youth

Subaward Period of Performance:		Amount Funded This Action:	Subaward No:
Start Date: Jul 1, 2016	End Date: Jun 30, 2017	\$ 230,877.00	RGF009152-B1
Effective Date of Amendment: Jul 1, 2016	Total Amount of Federal Funds Obligated to Date: \$ 435,150.00	Subject to FFATA: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

Amendment(s) to Original Terms and Conditions
This Amendment revises the above-referenced Research Subaward Agreement as follows:

Action:

This Amendment modifies the subaward as follows:

1. The period of performance of the subaward has been extended through 06/30/2017
2. The value of the award has been increased by \$230,877. The carryover of \$131,834 has also been approved.
3. Attachment 5 has been amended to include the detailed budget and Scope of Work
4. Attachment 6 is included to reflect the year 02 prime award

All other terms and conditions of this Subaward Agreement remain in full force and effect.

<p>By an Authorized Official of PTE:</p> <div style="display: flex; align-items: center;"> <div> <p>Digitally signed by Karen S. Niemeier DN: cn=Karen S. Niemeier, o=Children's Hospital Los Angeles, ou=FSR, email=lniemeier@chla.ucla.edu, c=US Date: 2017.09.14 17:54:35 -07'00' Adobe Acrobat DC version: 2015.006.302.43</p> </div> </div> <p>Karen S. Niemeier Executive Director, Research Administration</p>	<p>By an Authorized Official of Subrecipient:</p> <div style="display: flex; align-items: center;"> <div> <p>Sep 13, 2017</p> </div> </div> <p>Name: Christine Morris Title: Contracts & Grants Officer</p>
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Statement of Work

The Regents of the University of California, San Francisco (UCSF)

Year 2: 07/01/16-06/30/17

UCSF will:

- Participate on the PI and subcommittee calls as needed to monitor the implementation of the project.
- Participate in annual PI meeting.
- Secure ongoing IRB approval for the peri-pubertal study and post-pubertal study protocols.
- Designate a study coordinator to collect data, conduct chart abstractions, and track subjects.
- Recruit and consent [REDACTED] during the enrollment period.
- Recruit and consent [REDACTED] during the enrollment period.
- Designate a person to submit data, participate in regular calls with the CHLA data manager and clinical research manager, provide accrual reports, and comply with all data collection requirements, on a timely basis.
- Collect, enter, and submit baseline, 6 month, 12 month, and 24 month data including survey data, physiologic data (CRFs), etc. to CHLA, according to protocols.
- Ensure accurate data by quality assurance activities including double-checking data entry.
- Respond to data queries from CHLA in a timely manner.
- Ensure that all appropriate staff participate in all required trainings and supervision meetings.
- Participate in manuscript preparation and appropriate dissemination activities. Ensure that other sites are aware of any manuscripts and other activities related to this study.
- Provide official documentation, as required, that UCSF is in compliance with all local (city, county) and state/tribal requirements for licensing, accreditation, and certification or official documentation from the appropriate agency of the applicable State/tribal, county, or other governmental unit that licensing, accreditation and certification requirements do not exist.
- Submit invoices as required according to the approved budget.

AMOUNT OF CONTRACT: \$230,878 (\$218,792 + \$12,086 operating)

PAYMENT SCHEDULE: Monthly reimbursement based on invoices

PERIOD OF PERFORMANCE: 7/1/16-6/30/17

PROJECT#: 8011-RGF009152-00

Attachment 5

CHILDREN'S HOSPITAL LOS ANGELES DIVISION OF ADOLESCENT MEDICINE SUBCONTRACTOR BUDGET

Subcontracting Agency: The Regents of the University of California, San Francisco

Name of Program: The Impact of Early Medical Treatment in Transgender Youth

Budget Period: 07/01/16 - 06/30/17

Date Submitted: 12/06/2016

Line No.	A BUDGETED LINE ITEM	B Job Description	L; Annual Salary	u %FTE	E #MOS	F Yr 2 BUDGET	G Yr 1 Carryover BUDGET	H TOTAL BUDGET
	I. Personnel							-
	<i>(Please include Name & Period of Performance)</i>							
1	Stephen Rosenthal	Principal Investigator				\$38,871	\$5,553	\$44,424
2	Diane Ehrensaft	Co-investigator				\$10,260	\$2,565	\$12,825
-3	David Glidden	Co-investigator				\$7,404	\$1,86	\$9,255
4	Mere Abrams	Study Coordinator				\$42,815	\$17,192	\$60,007
5	TBN	Assistant Coordinator				\$0	\$57,149	\$57,149
	Subtotal Salaries					\$99,350	\$27,161	\$126,511
	Benefits @					\$32,816	\$36,356	
	TOTAL PERSONNEL					\$132,166	\$63,516	\$195,682
	II. Operating Expenses							
1	Data Network Fee					\$591	\$724	\$1,315
2	CCDSS					\$902	\$936	\$1,838
3	Travel					\$4,500	\$8,000	\$12,500
4	Patient reimbursement					\$4,005		\$4,005
5	Client Transportation					\$3,500	\$4,500	\$8,000
6	Supplies						\$5,500	
	TOTAL OPERATING EXPENSES					\$13,498	\$19,660	\$33,158
	TOTAL DIRECT COSTS					\$145,664	\$83,176	\$228,841
	III. INDIRECT COSTS @ 58.5% MTDC					\$85,213	\$48,658	\$133,871
	GRAND TOTAL					\$230,877	\$131,834	\$362,711

Research Subaward Agreement Amendment

Pass-Through Entity (PTE)		Subrecipient
Children's Hospital Los Angeles	Entity Name	The Regents of University of California, San Francisco
4650 Sunset Boulevard, Los Angeles, CA 90027-6062	Address including City, State, Zip+4 (Country, if non-US)	3333 California Street, Suite 315 San Francisco, CA 94118
Johanna Olson	Principal Investigator	Stephen Rosenthal
PTE Federal Award No: 5R01HD082554-04	Amendment No: 3	Federal Awarding Agency: NIH

Project Title: The Impact of Early Medical Treatment in Transgender Youth

Subaward Period of Performance:		Amount Funded This Action:	Subaward No:
Start Date: Jul 1, 2018	End Date: Jun 30, 2019	\$ 262,284.00	RGF009152-B4
Effective Date of Amendment: Jul 1, 2018	Total Amount of Federal Funds Obligated to Date: \$ 970,797.00	Subject to FFATA: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

Amendment(s) to Original Terms and Conditions
This Amendment revises the above-referenced Research Subaward Agreement as follows:

Action:

This Amendment modifies the subaward as follows:

1. The period of performance of the subaward has been extended through 06/30/2019
2. The value of the award has been increased by \$262,284
3. Any unobligated balance from prior years is not approved. Automatic carryover is not approved for this contract.
4. Attachment 5 has been amended to include the detailed budget and Scope of Work
5. Attachment 6 is included to reflect the year 04 prime award

All other terms and conditions of this Subaward Agreement remain in full force and effect.

<p>By an Authorized Official of PTE:</p> <div style="display: flex; justify-content: space-between; align-items: flex-end;"> <div style="text-align: center;"> Name: Karen S. Niemeier Title: Executive Director, Research Administration </div> <div style="text-align: center;"> <small>Digitally signed by Karen S. Niemeier DN: cn=Karen S. Niemeier, o=Children's Hospital Los Angeles, ou=TSRI, email=kniemeier@chla.usc.edu, c=US Date: 2018.10.31 07:02:09 -07'00' Adobe Acrobat DC version: 2015.006.30456</small> </div> <div style="border: 1px solid black; width: 100px; height: 30px; margin-top: 20px;"></div> <div style="text-align: center;">Date</div> </div>	<p>By an Authorized Official of Subrecipient:</p> <div style="display: flex; justify-content: space-between; align-items: flex-end;"> <div style="text-align: center;"> Name: Michelle Stevens Title: Contracts and Grants Officer </div> <div style="text-align: center;"> <small>DN: cn=Michelle K Stevens, Contracts and Grants Officer, o=The Regents of the University of California, San Francisco, ou=Office of Sponsored Research, Research Management Services, email=mmichelle@overseasof.edu, c=US Date: 2018.10.26 13:10:19 -07'00'</small> </div> <div style="border: 1px solid black; width: 100px; height: 30px; margin-top: 20px;"></div> <div style="text-align: center;">Date</div> </div>
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The Impact of Early Medical Treatment in Transgender Youth

Contact PI: Johanna L. Olson


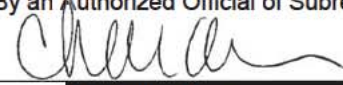
NIH/NICHHD Grant No: 5 R01HD082554-04

Project Period: 08/01/2015-06/30/2020

Budget Period: 07/01/2018-06/30/2019

Key Personnel	Title	Effort	No. of Months	Hourly Rate	Monthly Salary	Inst. Base	Salary	FB @11.6%	TOTAL
Stephen Rosental	PD/PI						\$ 35,398.32	\$ 4,106.21	\$ 39,504.53
Diane Ehrensaft	Co-I						\$ 13,527.72	\$ 1,569.22	\$ 15,096.94
David Glidden	Co-I						\$ 11,376.00	\$ 1,319.62	\$ 12,695.62
Total Salary & FB							\$ 60,302	\$ 6,995	\$ 67,297.08
Other Personnel	Title	Effort	No of Months	Hourly Rate	Monthly Salary	Inst. Base	Salary	FB @ 42%	TOTAL
Ivy Aslan	MD						\$ 2,028.00	\$ 851.76	\$ 2,879.76
TBD CRC	Study Coordinator						\$ 50,836.63	\$ 21,351.39	\$ 72,188.02
Mere Abrams	Study Coordinator						\$ 6,988.80	\$ 2,556.64	\$ 9,545.44
Kristian Gambardella	Study Coordinator						\$ 2,445.09	\$ 1,026.94	\$ 3,472.02
					\$ -	\$ -	\$ -	\$ -	\$ -
					\$ -	\$ -	\$ -	\$ -	\$ -
					\$ -	\$ -	\$ -	\$ -	\$ -
					\$ -	\$ -	\$ -	\$ -	\$ -
Total Other Personnel Costs							\$ 62,299	\$ 25,787	\$ 88,085.24
Travel									
Domestic Travel									\$ 2,000.00
Total Domestic Travel Costs									\$ 2,000.00
Materials and Supplies									
Binders, paper, small supplies									\$ 600.00
Total Materials and Supplies									\$ 600.00
Other Expenses									
Participant Incentives									\$ 6,100.00
Data Network									\$ 927.00
CCDSS									\$ 691.00
Total Other Expenses									\$ 7,718.00
SUBTOTAL DIRECT COST									\$ 165,700.32
MODIFIED TOTAL DIRECT COSTS (LESS CONSORTIUM/CONTRACTUAL COSTS)									\$ 165,100.32
INDIRECT COSTS (@ 58.50% F&A RATE)									\$ 96,583.69
TOTAL COSTS									\$ 262,284.00
NOA (Total Award)									\$ 262,284.00
(Over)/Under Budget									\$ (0.00)

Research Subaward Agreement Amendment

Pass-Through Entity (PTE)		Subrecipient	
Children's Hospital Los Angeles		Entity Name	The Regents of University of California, San Francisco
4650 Sunset Boulevard, Los Angeles, CA 90027-6062		Address including City, State, Zip+4 (Country, if non-US)	3333 California Street, Suite 315 San Francisco, CA 94118
Johanna Olson		Principal Investigator	Stephen Rosenthal
PTE Federal Award No: 5R01HD082554-03		Amendment No: 2	Federal Awarding Agency: NIH
Project Title: The Impact of Early Medical Treatment in Transgender Youth			
Subaward Period of Performance: Start Date: Jul 1, 2017 End Date: Jun 30, 2018		Amount Funded This Action: \$ 273,363.00	Subaward No: RGF009152-B3
Effective Date of Amendment: Jul 1, 2017	Total Amount of Federal Funds Obligated to Date: \$ 708,513.00		Subject to FFATA: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Amendment(s) to Original Terms and Conditions This Amendment revises the above-referenced Research Subaward Agreement as follows:			
Action: This Amendment modifies the subaward as follows: <ol style="list-style-type: none"> 1. The period of performance of the subaward has been extended through 06/30/2018 2. The value of the award has been increased by \$273,363 3. Attachment 5 has been amended to include the detailed budget and Scope of Work 4. Attachment 6 is included to reflect the year 03 prime award 			
All other terms and conditions of this Subaward Agreement remain in full force and effect.			
By an Authorized Official of PTE:  <small>Digitally signed by Karen S. Niemeier DN: cn=Karen S. Niemeier, o=Children's Hospital Los Angeles, ou=CHLA, email=kniemeier@chla.usc.edu, c=US Date: 2017.11.14 17:30:26 -08'00'</small> Name: Karen S. Niemeier Title: Executive Director, Research Administration		By an Authorized Official of Subrecipient:  Name: Christine Morris Title: Contracts & Grants Officer	

Statement of Work

The Regents of the University of California, San Francisco (UCSF)

Year 3: 07/01/17-06/30/18

UCSF will:

- Participate on the PI and subcommittee calls as needed to monitor the implementation of the project.
- Participate in annual PI meeting.
- Secure ongoing IRB approval for the peri-pubertal study and post-pubertal study protocols.
- Designate a study coordinator to collect data, conduct chart abstractions, and track subjects.
- Recruit and consent [REDACTED] during the enrollment period.
- Recruit and consent [REDACTED] during the enrollment period.
- Designate a person to submit data, participate in regular calls with the CHLA data manager and clinical research manager, provide accrual reports, and comply with all data collection requirements, on a timely basis.
- Collect, enter, and submit baseline, 6 month, 12 month, and 24 month data including survey data, physiologic data (CRFs), etc. to CHLA, according to protocols.
- Ensure accurate data by quality assurance activities including double-checking data entry.
- Respond to data queries from CHLA in a timely manner.
- Ensure that all appropriate staff participates in all required trainings and supervision meetings.
- Participate in manuscript preparation and appropriate dissemination activities. Ensure that other sites are aware of any manuscripts and other activities related to this study.
- Provide official documentation, as required, that UCSF is in compliance with all local (city, county) and state/tribal requirements for licensing, accreditation, and certification or official documentation from the appropriate agency of the applicable State/tribal, county, or other governmental unit that licensing, accreditation and certification requirements do not exist.
- Submit invoices as required according to the approved budget.

AMOUNT OF CONTRACT: \$273,363 (\$172,469 + \$100,894 operating)

PAYMENT SCHEDULE: Monthly reimbursement based on invoices

PERIOD OF PERFORMANCE: 7/1/17-6/30/18

PROJECT#: 8011-RGF009152-00

DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY	FROM	THROUGH
	7/1/17	6/30/18

List PERSONNEL (*Applicant organization only*)

Use Cal, Acad, or Summer to Enter Months Devoted to Project

Enter Dollar Amounts Requested (*omit cents*) for Salary Requested and Fringe Benefits

NAME	ROLE ON PROJECT	Cal. Mnths	Acad. Mnths	Summer Mnths	INST.BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTAL
Stephen Rosenthal	PD/PI					41,140	1,234	42,374
Diane Ehrensaft	Co-I					13,003	390	13,393
David Glidden	Co-I					11,220	5,161	16,381
Mere Abrams	CRC					54,740	31,732	86,473
SUBTOTALS →						120,104	38,518	158,621

CONSULTANT COSTS

EQUIPMENT (*Itemize*)SUPPLIES (*Itemize by category*)

TRAVEL

2,061

INPATIENT CARE COSTS

OUTPATIENT CARE COSTS

ALTERATIONS AND RENOVATIONS (*Itemize by category*)OTHER EXPENSES (*Itemize by category*)

Data network / CCDSS \$1699

Outpatient Labs \$6225

Participant Incentives \$3137; Participant Transportation \$726

11,787

CONSORTIUM/CONTRACTUAL COSTS

DIRECT COSTS

SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD (*Item 7a, Face Page*)

\$ 172,469

CONSORTIUM/CONTRACTUAL COSTS

FACILITIES AND ADMINISTRATIVE COSTS

TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD

\$ 172,469



University of California
San Francisco

Human Research Protection Program Institutional Review Board (IRB)

Expedited Review Approval

Principal Investigator
Stephen M Rosenthal

Type of Submission: Submission Correction for Initial Review Submission Packet
Study Title: The Impact of Early Medical Treatment in Transgender Youth

IRB #: 16-19371
Reference #: 166183

Committee of Record: Parnassus Panel

Study Risk Assignment: Minimal

Approval Date: 07/09/2016 **Expiration Date:** 07/08/2017

Regulatory Determinations Pertaining to this Approval:

This research satisfies the following condition(s) for the involvement of children:

45 CFR 46.404, 21 CFR 50.51: Research not involving greater than minimal risk.

Parental Permission and Assent:

The permission of one parent or guardian is sufficient.
The assent of the children will be obtained.

Individual Research HIPAA Authorization is required of all subjects. Use the Permission to Use Personal Health Information for Research form.

A waiver of HIPAA Authorization and consent is acceptable for the recruitment procedures to identify potential subjects. The recruitment procedures involve routine review of medical or other records, do not adversely affect the rights and welfare of the individuals, and pose minimal risk to their privacy, based on, at least, the presence of the following elements:

(1) an adequate plan to protect the identifiers from improper use and disclosure; (2) an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, or a health or research justification for retaining the identifiers was provided or such retention is otherwise required by law; (3) adequate written assurances that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the requested information would be permitted by the Privacy Rule; (4) the research could not practicably be conducted without the waiver; and (5) the study recruitment could not practicably be conducted without access to and use of the requested information. Study participants will sign a consent form prior to participation in the study.

This submission was eligible for expedited review as:

Category 5: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis)

Category 7: Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social

behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies

All changes to a study must receive UCSF IRB approval before they are implemented. Follow the [modification request](#) instructions. The only exception to the requirement for prior UCSF IRB review and approval is when the changes are necessary to eliminate apparent immediate hazards to the subject (45 CFR 46.103.b.4, 21 CFR 56.108.a). In such cases, report the actions taken by following these [instructions](#).

Expiration Notice: The iRIS system will generate an email notification eight weeks prior to the expiration of this study's approval. However, it is your responsibility to ensure that an application for [continuing review](#) approval has been submitted by the required time. In addition, you are required to submit a [study closeout report](#) at the completion of the project.

For a list of [all currently approved documents](#), follow these steps: Go to My Studies and open the study – Click on Informed Consent to obtain a list of approved consent documents and Other Study Documents for a list of other approved documents.

San Francisco Veterans Affairs Medical Center (SFVAMC): If the SFVAMC is engaged in this research, you must secure approval of the VA Research & Development Committee in addition to UCSF IRB approval and follow all applicable VA and other federal requirements. The UCSF IRB [website](#) has more information.

University of California, San Francisco
CONSENT/PERMISSION/ASSENT¹ TO PARTICIPATE IN A RESEARCH STUDY

The Impact of Early Medical Treatment in Transgender Youth
Trans Youth Care – Cross-Sex Hormone Cohort

Subject's Name: _____	
UCSF#: _____	Birth Date: _____

You are invited to participate in a research study conducted by Stephen Rosenthal, MD, from the Department of Pediatric Endocrinology at the University of California, San Francisco. This research is sponsored by the Eunice Kennedy Shriver National Institute of Child Health and Human Development at the National Institutes of Health. Participation in this study is completely voluntary.

The purpose of the study is to evaluate

[REDACTED]

If you volunteer to participate in this study, your participation

- [REDACTED]

It is possible that some questions in the survey may make you feel uncomfortable. If you do not feel comfortable answering a question, you can choose not to answer that question or you can stop filling out the questionnaire. There is the potential of accidental release of confidential information. To protect against this risk, your name and any other personal identifying information will not be

¹ This form also serves as the permission form for the parent(s) to read and sign. In this case, "You" refers to your child.

shared with anyone else. We will use a secret code on your surveys and forms, and the list that links your name and the secret code is kept in a password-protected file on the UCSF computer network. There may be additional risks to participation in this study that we do not know about and therefore cannot describe.

You should not expect any direct benefit as a result of participating in this research; however, the information that we learn from this research can help us improve care for transgender youth in the future. The alternative to participation is to not participate.

In consideration for your time participating in this research, the study team would like to offer you payment. The payments for participation are as follows: \$100 for the first visit and \$50 for each visit after that; if you participate in all visits, the total amount is \$300.

In addition to payments, and in consideration of the expenses you may have related to participation in the research, you or a family member or friend you designate will receive up to \$10 in expense reimbursement per visit for your participation in the study. You can be reimbursed for parking and/or transportation. To receive reimbursements, you will need to provide a name and date of birth. For each expense, you will also need to submit receipts or submit a mileage reimbursement form. Reimbursements are not reported to the IRS.

All personal information collected for payments or reimbursement is stored in a secure fashion and will be kept completely confidential.

This study includes procedures that are also a part of standard treatment. The cost of these procedures will be billed to your insurance or other third-party payer. Your family may be responsible for any co-pays or deductibles.

Only the research team will know that you are a research subject and have access to the information you provide. You will not be identified in publications of the research results. Authorized representatives of the Department of Health and Human Services and the UCSF Institutional Review Board may review subject records but are bound by rules of confidentiality not to reveal your identity. To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances:

- voluntary disclosure by researchers of information on such things as child or elder abuse, reportable communicable diseases, or possible threat to self or others.

A Certificate of Confidentiality does not represent an endorsement of the research study by the Department of Health and Human Services or the National Institutes of Health.

Your choice about whether or not to participate will have no effect on your care, services or benefits at the University of California, San Francisco. If you agree to participate, but later decide to withdraw from this study, you may do so without affecting your rights to health care, services or other benefits at UCSF.

You may be removed from the study by the investigator to protect your health or if other situations arise that make it necessary to do so. If you experience certain side effects such as depression, anxiety, or emotional distress because of your participation, you may have to drop out even if you would like to continue. The investigator, Dr. Rosenthal, will make the decision and let you know if it is not possible for you to continue. The decision may be made either to protect your health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate.

If there is significant new information found during the course of the study or the research plan is changed in a way that might affect your decision to continue participating in the study, you will be informed and your consent to continue participating in the study may be requested.

If you have questions about the research or wish to report a concern or complaint about the research, the Principal Investigator, Dr. Rosenthal, may be reached at 415-476-2266. You may withdraw from this study at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have questions regarding the rights of research subjects or if you have complaints or concerns about the research and cannot reach the Principal Investigator; or just want to talk to someone other than the Investigator, you may call the UCSF Human Subjects Protection Program at 415-476-1814.

Contact for future research

May someone from UCSF contact you to invite you to participate in future research? Please provide your initials beside your decision.

_____ Yes _____ No [for subject to complete, if the subject is 14 years or older]

_____ Yes _____ No [for parent to complete, if subject is a minor]

SIGNATURE OF RESEARCH SUBJECT (If the subject is 14 years or older)

Your signature below indicates

- You have read this document and understand its meaning;
- You have had a chance to ask questions and have had these questions answered to your satisfaction;
- You consent/assent to your participation in this research study; and
- You will be given a signed copy of this form and a signed copy of the HIPAA authorization form.

Print Name of Subject

Signature of Subject

Date

SIGNATURE OF PARENT(S)/LEGAL GUARDIAN(S) (If the subject is a minor)

Your signature(s) below indicates

- You have read this document and understand its meaning;
- You have had a chance to ask questions and have had these questions answered to your satisfaction;
- You agree to your child's participation in this research study; and
- You will be given a signed copy of this form and a signed copy of the HIPAA authorization form.

Print Name(s) of Parent(s)/Legal Guardian(s)

Signature of Parent/Legal Guardian

Date

Signature of Parent/Legal Guardian

Date

SIGNATURE OF INDIVIDUAL OBTAINING CONSENT

I have explained the research to the subject and/or the subject's parent(s)/legal guardian(s) and have answered all of their questions. I believe that they understand all of the information described in this document and freely give consent/permission/assent to participate.

Print Name of Individual Obtaining Consent

Signature of Individual Obtaining Consent

Date

University of California, San Francisco
CONSENT/PERMISSION/ASSENT¹ TO PARTICIPATE IN A RESEARCH STUDY

The Impact of Early Medical Treatment in Transgender Youth
Trans Youth Care – Blocker Cohort

Subject's Name: _____	
UCSF#: _____	Birth Date: _____

You are invited to participate in a research study conducted by Stephen Rosenthal, MD, from the Department of Pediatric Endocrinology at the University of California, San Francisco. This research is sponsored by the Eunice Kennedy Shriver National Institute of Child Health and Human Development at the National Institutes of Health. Participation in this study is completely voluntary.

The purpose of the study is to evaluate

[REDACTED]

If you volunteer to participate in this study, your participation will

[REDACTED]

¹ This form also serves as the permission form for the parent(s) to read and sign. In this case, "You" refers to your child.

[REDACTED]

It is possible that some questions in the survey may make you feel uncomfortable. If you do not feel comfortable answering a question, you can choose not to answer that question or you can stop filling out the questionnaire. There is the potential of accidental release of confidential information. To protect against this risk, your name and any other personal identifying information will not be shared with anyone else. We will use a secret code on your surveys and forms, and the list that links your name and the secret code is kept in a password-protected file on the UCSF computer network. There may be additional risks to participation in this study that we do not know about and therefore cannot describe.

You should not expect any direct benefit as a result of participating in this research; however, the information that we learn from this research can help us improve care for transgender youth in the future. The alternative to participation is to not participate.

In consideration for your time participating in this research, the study team would like to offer you payment. The payments for participation are as follows: \$100 for the first visit and \$50 for each visit after that; if you participate in all visits, the total amount is \$300.

In addition to payments, and in consideration of the expenses you may have related to participation in the research, you or a family member or friend you designate will receive up to \$10 in expense reimbursement per visit for your participation in the study. You can be reimbursed for parking and/or transportation. To receive reimbursements, you will need to provide a name and date of birth. For each expense, you will also need to submit receipts or submit a mileage reimbursement form. Reimbursements are not reported to the IRS.

All personal information collected for payments or reimbursement is stored in a secure fashion and will be kept completely confidential.

This study includes procedures that are also a part of standard treatment. The cost of these procedures will be billed to your insurance or other third-party payer. Your family may be responsible for any co-pay or deductibles.

Only the research team will know that you are a research subject and have access to the information you provide. You will not be identified in publications of the research results. Authorized representatives of the Department of Health and Human Services and the UCSF Institutional Review Board may review subject records but are bound by rules of confidentiality not to reveal your identity. To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. You should understand that a Certificate of Confidentiality does not prevent you or a

member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances:

- voluntary disclosure by researchers of information on such things as child or elder abuse, reportable communicable diseases, or possible threat to self or others.

A Certificate of Confidentiality does not represent an endorsement of the research study by the Department of Health and Human Services or the National Institutes of Health.

Your choice about whether or not to participate will have no effect on your care, services or benefits at the University of California, San Francisco. If you agree to participate, but later decide to withdraw from this study, you may do so without affecting your rights to health care, services or other benefits at UCSF.

You may be removed from the study by the investigator to protect your health or if other situations arise that make it necessary to do so. If you experience certain side effects such as depression, anxiety, or emotional distress because of your participation, you may have to drop out even if you would like to continue. The investigator, Dr. Rosenthal, will make the decision and let you know if it is not possible for you to continue. The decision may be made either to protect your health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate.

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If you have questions about the research or wish to report a concern or complaint about the research, the Principal Investigator, Dr. Rosenthal, may be reached at 415-476-2266. You may withdraw from this study at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have questions regarding the rights of research subjects or if you have complaints or concerns about the research and cannot reach the Principal Investigator; or just want to talk to someone other than the Investigator, you may call the UCSF Human Subjects Protection Program at 415-476-1814.

Contact for future research

May someone from UCSF contact you to invite you to participate in future research? Please provide your **initials** beside your decision.

_____ Yes _____ No [for subject to complete, if the subject is 14 years or older]

_____ Yes _____ No [for parent to complete, if subject is a minor]

SIGNATURE OF RESEARCH SUBJECT (If the subject is 14 years or older)

Your signature below indicates

- You have read this document and understand its meaning;
- You have had a chance to ask questions and have had these questions answered to your satisfaction;
- You consent/assent to your participation in this research study; and
- You will be given a signed copy of this form and a signed copy of the HIPAA authorization form.

Print Name of Subject

Signature of Subject

Date

SIGNATURE OF PARENT(S)/LEGAL GUARDIAN(S) (If the subject is a minor)

Your signature(s) below indicates

- You have read this document and understand its meaning;
- You have had a chance to ask questions and have had these questions answered to your satisfaction;
- You agree to your child's participation in this research study;
- You agree to your own participation in this research study; and
- You will be given a signed copy of this form and a signed copy of the HIPAA authorization form.

Print Name(s) of Parent(s)/Legal Guardian(s)

Signature of Parent/Legal Guardian

Date

Signature of Parent/Legal Guardian

Date

SIGNATURE OF INDIVIDUAL OBTAINING CONSENT

I have explained the research to the subject and/or the subject's parent(s)/legal guardian(s) and have answered all of their questions. I believe that they understand all of the information described in this document and freely give consent/permission/assent to participate.

Print Name of Individual Obtaining Consent

Signature of Individual Obtaining Consent

Date